



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 190

[Docket No. FDA-2022-D-0281]

Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-market Notification; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-market Notification.” The draft guidance, when finalized, will advise the dietary supplement industry of our intent to exercise enforcement discretion, for a limited time and in limited circumstances, regarding the requirement to submit a new dietary ingredient (NDI) notification prior to marketing. The purpose of the policy is to encourage manufacturers and distributors of certain NDI-containing dietary supplements to correct any past failures to submit a required NDI notification.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-D-0281 for "Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-market Notification." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

Submit comments on the information collection under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by

selecting “Currently under Review--Open for Public Comments” or by using the search function. The title of this proposed collection is “Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-market Notification; Draft Guidance for Industry.”

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Laura Rich, Office of Dietary Supplement Programs (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-8152; or Alexandra Jurewitz, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-market Notification.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any

person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The draft guidance, when finalized, will advise manufacturers and distributors of certain NDI-containing dietary supplements (namely, those that are subject to the premarket notification requirement and are being marketed without such a notification) of FDA's intent to exercise enforcement discretion for such firms to submit a late NDI notification for a limited time and in limited circumstances.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

III. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the
Requirement for Pre-market Notification

OMB Control Number 0910-NEW

This draft guidance, when finalized, is intended to advise the dietary supplement industry of our intent to exercise enforcement discretion, for a limited time and in limited circumstances, regarding the requirement to submit an NDI notification prior to marketing. The purpose of the policy is to encourage manufacturers and distributors of certain NDI-containing dietary supplements to correct any past failures to submit an NDI notification as required by § 190.6 (21 CFR 190.6). The proposed information collection requests that manufacturers and distributors who submit a late NDI notification under the enforcement discretion policy in the draft guidance supplement the notification with the following additional information: (1) a copy of the current label for the dietary supplement containing the NDI and (2) documentation to demonstrate the date that the dietary supplement was first introduced or delivered for introduction into interstate commerce.

We are developing a new submission type in the CFSAN Online Submission Module that will be used for late notifications submitted under the temporary enforcement discretion policy if the draft guidance is finalized. A draft screenshot of the questions specific to late notifications is available for comment at <https://www.fda.gov/food/new-dietary-ingredients-ndi-notification-process/how-submit-notifications-new-dietary-ingredient>.

Description of Respondents: The respondents to this collection of information are manufacturers and distributors in the dietary supplement industry; specifically, firms that failed

to comply with the NDI notification requirements in § 190.6 and that wish to take advantage of FDA's temporary enforcement discretion policy to submit a late NDI notification.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated One-Time Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden per Response (in hours) (18 minutes)	Total Hours
Submit product label and documentation of date of introduction into interstate commerce to FDA	3,500	1	3,500	0.30 (18 minutes)	1,050

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates in table 1 are based on our experience with our current NDI program. We estimate that 3,500 respondents will submit their product labels and documentation of dates of introduction into interstate commerce and that each respondent will submit 1 product label and corresponding documentation of date of introduction into interstate commerce. We further estimate that preparing and submitting each response will take approximately 0.30 hour (18 minutes), resulting in a total reporting burden of 1,050 hours (3,500 responses × 0.30 hour). This will be a temporary collection of information, as we expect to conduct this program for 6 months.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in § 190.6 have been approved under OMB control number 0910-0330.

Dated: May 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-10942 Filed: 5/19/2022 8:45 am; Publication Date: 5/20/2022]